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(54) Compression screw for a joint endoprosthesis.

A compression bone screw apparatus (10) includes an elongated cylindrical shaft member (23) with a first smaller diameter portion that is of generally uniform cylindrical configuration, and a second enlarged diameter annular proximate end portion (27). An internal bore (28) extends longitudinally along the length of the shaft member (23), being open ended so that a driver tool (19) can extend through the elongated cylindrical shaft member (23) during installation of the compression bone screw apparatus (10). A generally cylindrical lag screw member (30) is slidably mounted in telescoping fashion upon the shaft member (23) at a position spaced from the annular proximate end portion (20) thereof. Splines prevent rotation of the shaft (23) with respect to the lag (30) as the lag (30) slides upon the shaft (23) to increase the overall combined length of the assembled shaft and lag screw (10). Stops, preferably in the form of abutting shoulders (27,33) of the respective shaft (23) and lag (30) screw member abut when the apparatus (10) is fully extended so that continued threading of the lag (30) into a surgical opening (17,18) in bone (T) causes a compression load across a fracture (14). The small compressing load discourages disassembly of the apparatus (10) when subsidence oc-

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The present invention relates to orthopaedic fixation devices for use with modular joint implants and more particularly relates to an improved compression screw apparatus for retaining a joint endoprosthesis in a bone wherein the screw is held in position by a small compressing load, and applied by a part of the implant assembly. The compression load prevents a screw backing out as the prosthesis sinks into the bone (subsides). The screw is particularly suitable for use with tibial prostheses.

Fixation screws and nails used in modular joint replacement can sometimes "back out" of proper operative position if the implant subsides. Revision surgery can be required to reassemble and/or replace all or part of the implant device. Several prior art devices used to treat fractures of the hip are discussed and illustrated in an article entitled "Hip Nails for All occasions" by Raymond G. Tronzo, in the Orthopaedic Clinics of North America (Vol. 5, No. 3, July 1974).

A number of bone screws commercially available or the subject of publications which are retained in position by means of nuts, threads, pins, retaining rings, welds or lock washers. These retainers physically secure the screw in position. Certain disadvantages are present in known mechanical screw retainers in used for fixation of a modular joint replacement. Such mechanical retainers would be subject to fatigue loads, which have a high likelihood of causing failure of the mechanical retention used, resulting in a disassembly of the implant device.

Another disadvantage of prior fixation system is that in most cases they require additional surgical time for use and are subject to error. The potential negative effects of prolonged surgery include numerous complications, and errors that may lead to failure which injures the patient, requiring additional surgery.

Several orthopaedic fixation devices have been patented. The Asnis system shown in US Patents 4383527 and 4450835 uses one or more rigid lag screws which are installed across a fracture site over guide pins to rigidly secure the bone fragments in close proximity to one another.

Other devices for the fixation of fractures are disclosed in patent specifications. A variable length fixation device for insertion into a hole formed in tow or more bone fragments includes a barrel portion and a fastener element. The barrel portion is secured to an inside surface of the hole in a proximal one of the bone fragments. The fastener element is telescopically mounted to the barrel portion and is extendible into the distal of one of the bone fragments. The assembly prevents lateral movements of the distal fragments, relative to the proximate fragment, while allowing axial relative movement (ie. linear movements along the longitudinal axis of the fastener element) to occur. In one embodiment, the fastener element is a cannulated bone screw having a hexagonal shaped cross

section on one end which is telescopically received into the hex shape interior of the hollow barrel portion. Two components are preferably permanently joined to form a one-piece assembly having a variable overall length. The fixation device is substantially insertable in its entirety into a hole which extends across the fracture site.

Other patent specificatins that relate generally to compression screws include US Patent 4776329, entitled "Resorbable Compression Screw and Method", wherein a method for repairing a bone fracture with a compression screw assembly is provided. First and second non-resorbable compression members are positioned so that the head portion of the compression screw can protrude from the surface of the second non-resorbable compression member after further compression is effected by the normal healing process. At least the head portion of the screw is formed of a material that resorbs upon contact with body fluids.

In US Patent No. 4530355 there is provided a compression screw assembly for applying compression to a fracture bone. The apparatus includes a lag screw, a compression plate including a hollow barrel member adapted to receive the lag screw in at least one fixed orientation, a wrench assembly adapted to releasably engage the lag screw in axial alignment therewith, and apparatus having surface contours complimentary with the outer surface of the lag screw and inner surface of the barrel member for being optionally insertable into the barrel member to prevent axial rotation of the lag screw with respect to the barrel member.

Another compression screw system is the subject of US Patent 4095591, wherein an extension is provided for being non-rotatably fixed to a lag screw that is to be anchored to the head of a femur or other bone in a manner to be anchored to the head of a femur or other bone in a manner so as to allow compression to be applied to the fracture. The extension extends outward of the bone when attached to the lag screw and when the lag screw is anchored to the bone to allow a compression plate to be easily positioned thereon, the cross section of the extension is substantially the same as the cross section of the lag screw to allow the compression plate to be easily and quickly passed onto the lag screw from the extension once the compression plate has been positioned on the extension.

Other fixating devices which uses bone screws are disclosed in US Patent No. 4432258, entitled "Compression Hip Screw Apparatus"; US Patent No. 4530355, entitled "Compression Screw Assembly"; US Patent No. 4612920, entitled "Compression Hip Screw"; US Patent No. 4621629, entitled "Compression Hip Screw"; US Patent No. 4623923, entitled "Axial Compression Device"; US Patent No. 4653489, entitled "Fenestrated Hip Screw and Method of Augmented Fixation"; US Patent No. 4657001, entitled

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"Anti-rotational Hip Screw"; US Patent No. 4791918, entitled "Femoral-Neck Implant"; US Patent No. 4794919, "Fixating Device"; and US Patent No. 4858601, entitled "Adjustable Compression Bone Screw".

The present invention provides an improved compression bone screw apparatus, having particular utility as a compression screw for a joint endoprosthesis. The apparatus is designed to mitigate the problem of preventing fixation screws from backing out when a modular joint replacement implant subsides

The present invention avoids screw back out by compressing when the modular joint implant subsides. This is accomplished by a two-piece design of the screw apparatus which allows compression from the fully extended position when a small compressing load is applied to the screw.

The screw apparatus of the present invention also features an angled or dished, generally convex top surface of the head portion which allows the plate into which the screw is fixed to tilt about the spherical radius centre of the head without the screw protruding above the plate. This reduces the chance that tilting subsidence will lead to screw back out and disassembly of the device.

The above discussed several prior art device include screws which are retained in position by means of nuts, threads, pins, retaining rings, welds, lock washers, metal deformation (peening for example). All of these securing means physically secure the screw in position. With the present invention, the screw is not held in position except by means of small compression load, applied by a portion of the joint implant assembly. With the present invention, the problem of fatigue loads which are associated with the above-discussed prior art designs, is eliminated. Fatigue loads have a high likelihood of causing failure of the retention means of any system, which may lead to a disassembly of the entire device and mechanical failure. The present invention will allow relief of fatigue loads which may occur in subsidence, thus avoiding disassembly and mechanical failure of the device.

Other disadvantages of similar devices is that in most instances they require additional surgical time for use and are subject to error. This introduces the potential negative effects of prolonged surgery and include increased incidence of commercial complications. Surgical errors may also lead to failures which injure the patient and may require additional surgery.

The present invention thus provides an improved compression screw bone apparatus having particular utility in use with a joint endoprosthesis. The apparatus includes an elongated cylindrical shaft member that has a first small diameter portion and an enlarged diameter annular proximate end or head portion. An internal bore extends longitudinally along

the length of the shaft member, and a generally cylindrical lag screw with an internal lag bore is slidably mounted in telescoping fashion upon the shaft member and at a position spaced from the annular proximate end portion thereof. External threads are provided on the lag screw for engaging a surgically formed opening in bone tissue.

The lag screw bore is elongated so that the shaft can extend into the lag screw socket, along substantially the entire length of the lag screw if necessary. The lag slides to a fully extended position upon the shaft and lag screw member to maximum diameter. The lag then bottoms out and can extend no further, and compression loading is then provided. Thus when the assembly is fully extended into a surgical opening a compression load is placed across the fracture.

For a further understanding of the nature and objects of the present invention, reference should be had to the following description, taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals, and wherein;

Figure 1 is a schematic side sectional view illustrating the drilling of a opening in bone tissue prior to insertion of the compression screw apparatus of the present invention;

Figure 2 is a sectional elevational view of the preferred embodiment of the apparatus of the present invention illustrating placement;

Figure 3 is sectional view of the preferred embodiment of the apparatus of the present invention; Figure 4 is bottom or distal end view of the preferred embodiment of the apparatus of the present invention:

Figure 5 is a top or proximate end view of the preferred embodiment of the apparatus of the present invention:

Figure 6 is a side view of a driver tool used to install the compression screw apparatus of Figures 2 - 5.

Figures 7A - 7C are sequential sectional side views illustrating installation of the preferred embodiment of the apparatus of the present invention using a driver tool;

Figure 8 is a partial view of the preferred embodiment of the apparatus of the present invention illustrating the proximate head portion thereof.

Figure 9 is a fragmentary view of the preferred embodiment of the apparatus of the present invention illustrating the sliding lag sleeve portion thereof:

Figure 10 is a schematic side fragmentary view of the preferred embodiment of the apparatus of the present invention illustrating plate portion and screw portions geometry when the screw tilts with respect to the plate portion;

Figure 11 is an exploded view of a second embodiment of the apparatus of the present invention; Figure 12 is a side view of a second embodiment

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of the apparatus of the present invention;

Figure 13 is a distal or bottom end view of a second embodiment of the apparatus of the present invention; and

Figures 14A - 14C are sequential sectional side views illustrating installation of the second embodiment of the apparatus of the present invention.

Figures 1 - 10 illustrate generally the preferred embodiment of the apparatus of the present invention designated generally by the numeral 10. In Figure 1, there can be seen a patient's femur 11 and illustrating schematically the neck 12, ball 13 and a fracture site 14. A drill 15 is shown in fragmentary view as supporting an elongated drill bit 16 which is forming a pair of spaced apart openings 17, 18. In Figure 2, a driver tool 19 (see Figure 6) is used by the surgeon to thread the apparatus 10 into operating position within one of the surgically formed openings 17, 18.

A driver tool extends into an open ended bore 28 that extends longitudinally along the central axial portion of shaft 23 which has a proximate end 20 portion with an angled or convex top 21. The shaft 23 as aforementioned is hollowed, providing a central, longitudinally extending cylindrical bore 28 that can accommodate driver tool 19.

A curved transition section 24 forms an interface between the enlarged head 20 and shaft 23. The shaft 23 is generally cylindrical, providing a cylindrical outer surface that extends between the transition section 24 and shoulder 26 which is an annular shoulder defining a change in diameter of the shaft 23 and communicating with an elongated diameter annular end portion 27.

A lag sleeve 30 is slidably and telescopically mounted upon shaft 23. Lag sleeve 30 provides at least one external thread 31. The proximate end or upper end 32 of lag 30 defines an opening 34 having an internal diameter that is substantially equal to the external diameter of shaft 23 above enlarged diameter portion 27, as shown in Figure 3. The upper end 32 of lag sleeve 30 defines thus a cylindrical sleeve 33 that closely fits and slides upon the shaft 23 above portion 27. An internal annular shoulder 35 defines a change in diameter of the internal bore 40 of lag 30. Shoulder 35 communicates with the inside surface of sleeve 33 and also with an enlarged diameter bore section 36 of bore 40. The lag sleeve can be expanded, for example by heating to install shaft 23 therein. Thus, upon assembly, there is a space 37 between the inner cylindrical wall 36 of lag 30 and the outer surface of shaft 23 when the shoulder 26 of shaft 23 and the shoulder 35 of lag 30 are spaced apart, as shown in Figures 3 and 7A - 7B. The lower end portion 41 of lag 30 provides a hexagonal socket 38 that communicates with bore 40, as shown in Figure 3.

Cylindrical bore 28 is sized to accommodate drive 19 and the driver 19 provides a hexagonal drive tip 42 that is sized to register in and fit a tooled hexagonal socket 38 (see Figures 7A - 7C). In this manner the surgeon uses the driver 19 to rotate the lag screw 30 portion of the apparatus 10. During use the surgeon inserts the distal end 41 of lag scree 30 into one of the openings 17, 18 formed in the bone tissue T, as shown in Figure 2. The surgeon then threads the lag 30 into the bone tissue at one of the openings 17 and 18. The lag 30 portion rotates with the driver and separately with respect to the shaft 23. This allows the lag 30 to continue to rotate after the head 20 portion abuts and registers against a bone plate, prosthesis, or simply at the outer surface of the patient's femur 11 as shown in Figure 2. By continuing to rotate the driver 19 and applying torque at the handle H, the surgeon continues to rotate the lag 30. However, frictional resistance between the bone tissue and the head 20 causes the head and shaft 23 to cease rotation and further advancement while the lag 30 continues to advance. This causes a resistance in torque to dramatically increase so that a compression load is placed in the tissue T, as shown by the arrows 43 in Figure 2.

The two-part apparatus 10 allows compression from the fully extended position (Figures 2 and 7C) when a small compressing load is applied to the screw. The apparatus 10 will allow relief of fatigue loads which may occur in subsidence, thus avoiding disassembly and mechanical failure of the device in the relevant range of subsidence (relevant range is defined as an insufficient amount of subsidence to require surgical replacement of a modular implant for reasons other than mechanical failure of the implant).

Figures 7A - 7C illustrate sequentially, the installation of the apparatus 10 of the present invention. The screw 10 is inserted into the surgical hole or opening. Initially, the enlarged end 27 registers with the stop 29 portion of the lag 30 (Figure 7A). The surgeon then rotates the handle H of the driver 19 rotating the threads 31 of the lag 30 in to the opening and continuing. As the screw head 20 begins to engage an endoprosthesis, or hone tissue, resistance causes the lag 30 to slide along the shaft 23, and intermediate sliding position being illustrated in Figure 7B.

Continued in advancement of the lag 30 into the surgical opening 17 or 18 causes the lag 30 to become fully extended so that the shoulder 26 of the shaft 23 engages the shoulder 35 of the lag 30, as shown in Figure 7C. At this point, the lag can slide no further with respect to the shaft 23, and the torque resistance dramatically increases. The shoulders 26 and 35 abut upon full extension (Figure 7C) to prevent further advancement, and the screw 10 will then "lag" (apply compression to the implant bone assembly).

In Figure 10, an endoprosthesis plate P is illustrated schematically in side view with the head 20 portion of the apparatus 10 being shown in various positions. The central longitudinal axis of the shaft 23 indicated by the letter "X" is illustrated in different

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angular positions with respect to the outer surface of the plate P as shown by the angles A and B in Figure 10. The use of an angled top 21 having the annular bevelled surface 22 allows the plate P into which the screw 10 is fixed to tilt about the spherical radius centre of the head 20 without the screw 10 protruding above the plate P. This reduces the chance that tilting subsidence will lead to screw back out and disassembly of the device.

Figures 11 - 13 and 14A - 14C illustrate an alternative embodiment of the apparatus of the present invention designated generally by the nuneral 50. The compression screw apparatus 50 includes a shaft body 51 having an upper proximate enlarged end 52 that includes an upper dished or convex surface defined by annular inclined surface 53. The upper end 52 of the shaft body includes a tool socket 54 which can be, for example, a hexagonal socket receptive of a driver such as 19 shown in Figure 6. In the embodiment of Figures 11-13, and 14A-14C, the driver registers with a closed socket that extends a short distance into the upper proximate end 52 of shaft body 51. The tool socket 54 would be symmetrically placed about the central longitudinal axis 55 of the shaft body so that torque can be imparted to the shaft body 51 using a driver 19, for example. Upper proximate enlarged end portion 52 includes a curved underside 56, and a curved transitional section 57 that meets with an elongated generally cylindrical portion of the shaft body as shown in Figure 11. The distal end 58 of the shaft body extends a short distance beyond a transverse opening 59 which accommodates pin 70. Lag screw member 60 slidably mounts upon shaft body 51 as the internal bore 62 of lag screw member 60 as an internal diameter portion that registers upon and slides upon the outer surface of shaft body 51, as shown in Figures 11, 12, and 14A - 14C. The bore wall 54 is enlarged at longitudinal grooves 65 which are sized and shaped to accommodate the exposed portion 74, 75 of pin 70, as shown in Figures 14A - 14C. The ends 74, 75 act as splines which engage in grooves 65 formed in the lag screw 60. The grooves 65 are open ended at the bottom 69 of lag screw member 60, but terminate at stop 66 which limit the extension of lag screw member 60 away from upper proximate enlarged end 52 of shaft body 51, the extended position being shown in Figure 14C wherein the pin 70, and more particularly the ends 74 and 75 thereof register with the stops 66.

Arcuate recesses 67, 68 can be provided at the bottom of lag screw member 60 so that pin 70 can be moved transversely into and out of transverse opening 59 when sleeve 60 assumes a retracted fully withdrawn position upon shaft 51, the position shown in Figure 14A.

Figures 14A - 14C illustrate the installation of compression screw apparatus 50. In Figure 14A, the lag screw 60 is in a fully retracted position, wherein

arrow 71 indicates a rotational torque that is imparted by the surgeon using a driver 19, for sample, to rotate the entire assembly 50. As the assembly 50 is rotated, the threads 63 of lag screw member 60 bite into the surrounding bone tissue T and advance the lag screw member 60 in the direction of arrows 72. In Figure 14B, a transitional position is shown wherein the lag screw member 60 has advanced about halfway between its fully retracted position of 14A and its fully extended position of 14C.

In Figure 14C, the lag screw member 60 is fully extended and the transverse pin 70 registers against stops 66 of grooves 65 limiting further movement of the lag screw. At this point, the surgeon continues to impart torque to the shaft 51 at the socket 54 using a driver 19, for example. As the transverse pin 70 abuts the stop 66, resistance to continued rotation dramatically increases and a tension load is placed in the apparatus 50, along the length thereof.

Parts List

- 10 Compression screw apparatus
- 11 Femur
- 12 Neck
- 13 Ball
- 14 Fracture site
- 15 Drill
- 16 Drill bit
- 17 Surgical opening
- 18 Surgical opening
- 19 Driver tool
- 20 Proximate end portion
- 21 Angled head
- 22 Annular inclined surface
 - 23 Shaft
 - 24 Transition
 - 25 Peripheral edge
 - 26 Annular shoulder
- 27 Enlarged diameter annular end portion
 - 28 Bore
 - 29 Lower stop
 - 30 Lag sleeve
 - 31 Threads
- 32 Upper end of lag
 - 33 Annular sleeve
 - 34 Internal cylindrical opening
 - 35 Annular shoulder
 - 36 Inner cylindrical wall
- 37 Space
 - 38 Hexagonal socket
 - 39 Frustro-conical section of bore
 - 40 Bore
 - 41 Lower end of lag
- 42 Hex drive
 - 50 Compression screw apparatus
 - 51 Shaft body
 - 52 Upper proximate enlarged end

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- 53 Annular inclined surface
- 54 Tool socket
- 55 Central longitudinal axis
- 56 Curved underside
- 57 Transition curved section
- 58 Distal end of shaft body
- 59 Transverse cylindrical opening
- 60 Lag screw member
- 61 Proximate end of lag screw
- 62 Lag screw bore
- 63 Lag screw threads
- 64 Bore wall
- 65 Longitudinal grooves
- 66 Stop
- 67 Arcuate recess
- 68 Arcuate recess
- 69 Distal end of lag screw
- 70 Transverse pin
- 71 Arrow, rotational movement
- 72 Arrow, linear movement
- H Handle
- X Axis
- B Angle
- A Angle
- P Plate
- T Tissue

Claims

- 1. A compression bone screw apparatus comprising:
 - a) an elongated cylindrical shaft member that includes a first smaller diameter portion and an enlarged diameter annular proximate end portion:
 - b) an internal bore extending longitudinally along the length of the shaft member;
 - c) a generally cylindrical lag screw member with an internal lag bore, and that is slidably mounted in telescoping fashion upon the shaft member and at a position spaced from the annular proximate end portion thereof;
 - d) external thread means on the lag screw for engaging a surgically formed opening in bone
 - e) the lag screw bore being elongated so that the shaft can extend into the lag screw socket along substantially the entire length of the lag screw; and
 - f) compression loading means for placing the assembly of the lag and shaft member in compression when the lag and member are fully extended with respect to each other to a maximum overall length.
- 2. Apparatus according to claim 1 wherein the elongated cylindrical shaft member includes a first

smaller diameter portion of generally uniform diameter as defined by a cylindrical outer surface of the first smaller diameter portion.

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- 3. Apparatus according to claim 1 or claim 2 wherein the lag screw member provides an internal lag screw bore of variable diameter.
- 4. Apparatus according to any one of claims 1 to 4 wherein the lag screw is shorter in length than the 10 shaft member.
 - 5. Apparatus according to any one of claims 1 to 4 wherein the internal shaft bore is open ended, extending the full length of the shaft member.
 - 6. Apparatus according to any one of claims 1 to 5 wherein the compression loading means comprises in part co-operating shoulders of the shaft member and lag screw which abut when the lag screw and shaft member telescope with respect to each other to a fully extended, maximum length position.
- Apparatus according to any one of claims 1 to 6 25 wherein the lag screw carries socket means at its distal end portion, and communicating with the internal bore of the lag screw.
- 30 Apparatus according to any one of claims 1 to 7 wherein the lag screw provides a socket at its lower, distal end portion and the assembled compression bone screw has a common internal bore that allows access to the socket via the enlarged internal annular proximate end portion. 35
 - 9. According to any one of claims 1 to 5 further including rotation prevention means, comprising spline means extending transversely from the distal end portion of the shaft and longitudinal groove means formed in the lag screw member and being adapted to register with said spline means.
 - 10. Apparatus according to claim 9 wherein said spline includes a pair of spaced apart longitudinally extending splines and a corresponding pair of spaced apart longitudinally grooves formed on the inside wall of the lag screw and communicating with the lag screw bore.
 - 11. Apparatus according to claim 9 or claim 10 wherein the elongated cylindrical shaft member includes a first smaller diameter portion of generally uniform diameter as defined by a cylindrical outer surface of the first smaller diameter portion.
 - 12. Apparatus according to any one of claims 9 to 11 wherein the shaft carries one or more splines at

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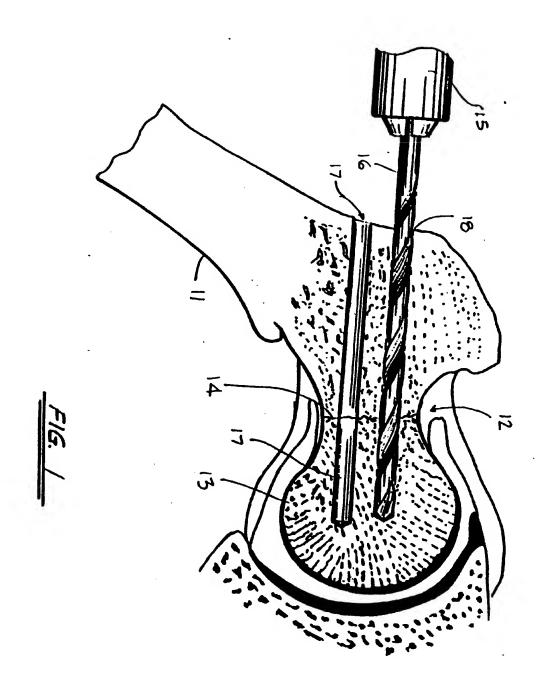
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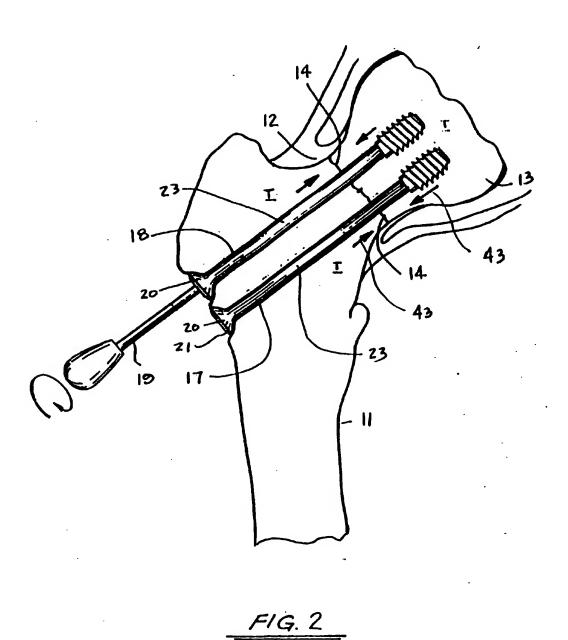
its lower end portion which engage corresponding grooves of the lag screw for preventing rotation of the lag screw with respect to the shaft member during rotation of the lag screw as occurs during installation.

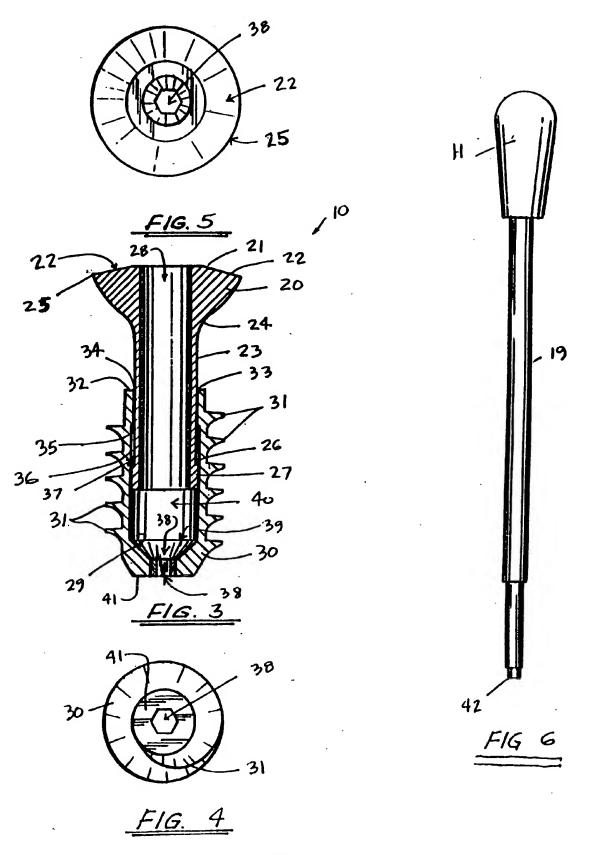
13. Apparatus according to any one of claims 9 to 12 wherein the cylindrical shaft member carries a transverse pin that extends beyond the outer surface of the shaft member at a position spaced away from the enlarged diameter annular proximate end portion, and the lag screw carries longitu-

dinally extending groove means for registering with the pin so that the pin can slide longitudinally with respect to the leg screw, but prevents rotation of the lag screw with respect to the shaft.

14. Apparatus as claimed in any one of claims 9 to 13 wherein the lag screw member has an internal bore of generally constant diameter and the longitundinal grooves extend only partially from the distal end, thereby providing stop means for limiting the telescopy movement of the lag screw member upon the cylindrical shaft.







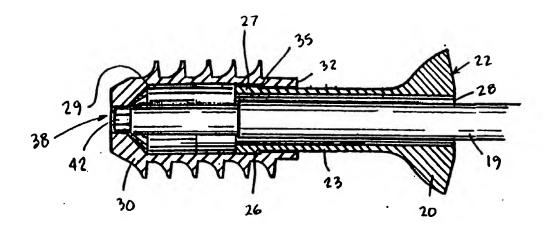
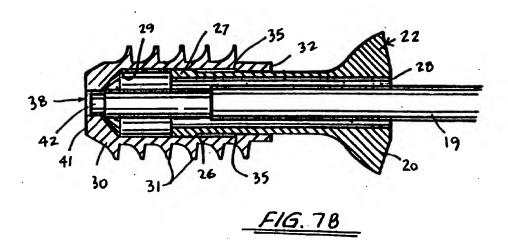


FIG. 7C



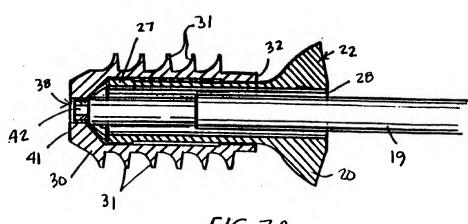
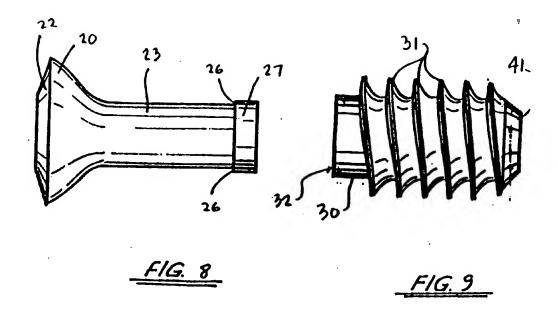


FIG. 7A



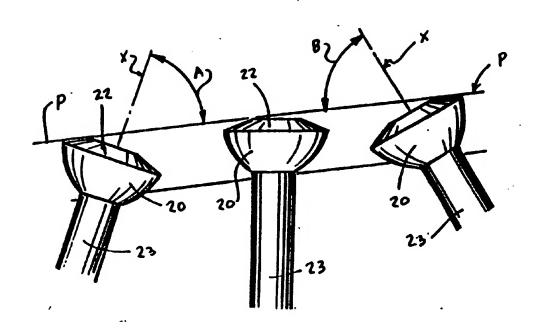
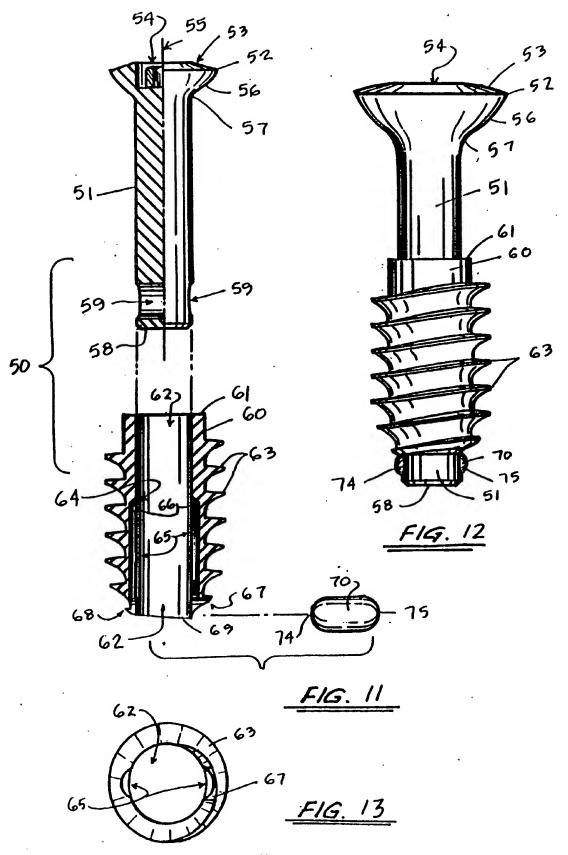
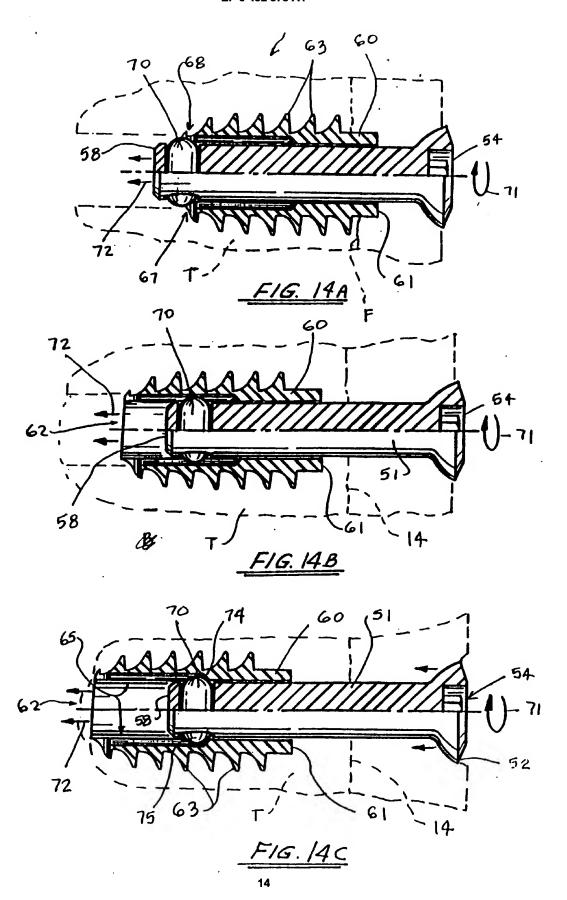


FIG. 10







EUROPEAN SEARCH REPORT

Application Number

EP 91 30 9731

		DERED TO BE RELEVANT	ľ	
Category	Citation of document with it of relevant pa	adication, where appropriate,	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	WO-A-8 906 940 (BIOMET)		1,2,5,6, 8,9,11	A61B17/58
	* page 10, line 17 - pa 1-3,11 *	ge 13, line 23; figures	-,-,-	
A	US-A-3 107 666 (CECERE)		1,2,5,6, 8,9,11,	
	* column 2, line 39 - c	olumn 3, line 8; figures	14	
۸.	US-A-2 121 193 (HANICKE * page 2, right column, column, line 43; figure	line 31 - page 3, left	1,2,5,11	
A	US-A-3 029 811 (YOST)	-	1,2,5,9, 11,13,14	
	* column 2, line 6 - 11			
4	US-A-3 530 854 (KEARNEY)		TECHNICAL FIELDS
١	EP-A-0 377 401 (MECRON)			SEARCHED (Int. Cl.5)
4,0	EP-A-0 085 493 (RICHARD	s)		A61B
	The present search report has be	en drawn up for all claims		
Place of search Date of completion of the search				Economic
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